## PATENT COOPERATION TREATY

RECEIVED

NOV 0 7 2005

From the INTERNATIONAL SEARCHING AUTHORITY

To: JANE MASSEY LICATA LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053	Docket System Status Report Docket Book	PCT  NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION  (PCT Rule 44.1)  Date of Mailing (day/month/year)  02 NOV 2005				
Applicant's or agent's file re	eference					
RU-0192		FOR FURTHER ACTION See paragraphs 1 and 4 below				
International application No PCT/US03/23867		International filing date (day/month/year) 30 July 2003 (30.07.2003)				
Applicant RUTGERS, THE STATE U	NIVERSITY					
Filing of amend	ments and statement under Article 19:	rch report has been established and is transmitted herewith. : sims of the international application (see Rule 46):				
	When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.					
	Where? Directly to the International Bureau of WIPO, 34, chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35					
For more detailed instructions, see the notes on the accompanying sheet.						
2. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.						
3. With regard to t	the protest against payment of (an) addi	tional fee(s) under Rule 40.2, the applicant is notified that:				
the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.						
no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.						
4. Reminders						
applicant wishes to avoid	d or postpone publication, a notice of wi Bureau as provided in Rules 90 bis.1	nal application will be published by the International Bureau. If the ithdrawal of the international application, or of the priority claim, must and 90 bis.3, respectively, before the completion of the technical				
Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.						
In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.						
See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.						
Name and mailing address of t	the ISA/US	Authorized office				
Mail Stop PCT, Attn. Commissioner for Pa		MINH TAM DAVIS				
P.O. Box 1450 Alexandria, Virginia	· · · · · · · · · · · · · · · · · · ·	15/15/15				
Facsimile No. (703) 305-3230		Telephone No. 57 -724600 (See notes on accompanying sheet)				
Form PCT/ISA/220 (April 2002	9	(See notes on accompanying sneer)				



# **PCT**

#### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RU-0192	FOR FURTHER ACTION		see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.					
International application No. PCT/US03/23867	International filing date (day/mo 30 July 2003 (30.07.2003)	nth/year)	(Earliest) Priority Date (day/month/year) 26 August 2002 (26.08.2002)					
Applicant RUTGERS, THE STATE UNIVERSITY								
This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.  This international search report consists of a total of sheets.								
This international search report consists of a total of sheets.  It is also accompanied by a copy of each prior art document cited in this report.								
Basis of the Report     a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.								
the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).  b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:								
contained in the intern	ational application in written form.							
	international application in computer re	adable form	n.					
	to this Authority in written form.							
= ' '	furnished subsequently to this Authority in computer readable form.							
the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.								
the statement that the i furnished.	nformation recorded in computer reada	ble form is	identical to the written sequence listing has been					
2. Certain claims were t	Certain claims were found unsearchable (See Box I).							
· —	Unity of invention is lacking (See Box II).							
	4. With regard to the title,							
	submitted by the applicant.	e.						
the text has been estab	lished by this Authority to read as follo	ws:						
5. With regard to the abstract,								
the text is approved as	submitted by the applicant.							
the text has been estab	lished, according to Rule 38.2(b), by the date of mailing of this international	is Authority Il search rep	y as it appears in Box III. The applicant may, oort, submit comments to this Authority.					
6. The figure of the drawings to	6. The figure of the drawings to be published with the abstract is Figure No.							
as suggested by the ap			None of the figures					
because the applicant	failed to suggest a figure.							
because this figure better characterizes the invention.								

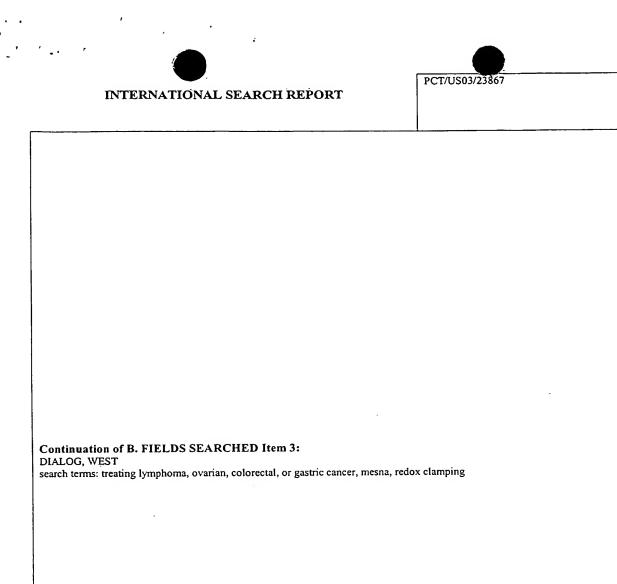
Form PCT/ISA/210 (first sheet) (July 1998)

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/23867

ACLASSIFICATION OF SUBJECT MATTER  IPC(7) : A61K 38/17  US CL : 514/12							
According to International Patent Classification (IPC) or to both national classification and IPC							
B. FIELDS SEARCHED  Minimum documentation searched (classification system followed by classification symbols)  U.S.: 424/488							
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched							
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet							
C. DOC	UMENTS CONSIDERED TO BE RELEVANT						
Category *	Citation of document, with indication, where ap		Relevant to claim No.				
X X, E	US 6,497,904 B2 (SINGH) 24 December 2002 (24.12 column 8, line 58. US 20030036513 A1 (MERMELSTEIN et al) 20 Feb	1-4					
	•						
	documents are listed in the continuation of Box C.	See patent family annex.					
Special categories of cited documents:  "A" document defining the general state of the art which is not considered to be of particular relevance  "E" earlier application or patent published on or after the international filing date		"T" later document published after the inte date and not in conflict with the applic principle or theory underlying the inve "X" document of particular relevance; the considered novel or cannot be conside when the document is taken alone	ation but cited to understand the ntion				
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  "O" document referring to an oral disclosure, use, exhibition or other means		"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art					
"P" document published prior to the international filing date but later than the priority date claimed		"&" document member of the same patent	family				
Date of the actual completion of the international search		Date of mailing of the international search report  0 2 NOV 2005					
13 October 2005 (13.10.2005)			~ NUV ZUUD				
Name and mailing address of the ISA/US  Mail Stop PCT, Atm: ISA/US  Commissioner of Patents		Authorized officer MINH TAM DAVIS					
P.O. Box 1450 Alexandria, Virginia 22313-1450		Telephone No. 571-272-1600	von en fr				
Facsimile No. (703) 305-3230 Form PCT/ISA/210 (second sheet) (July 1998)							



Form PCT/ISA/210 (second sheet) (July 1998)

#### NOTESTO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

# INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

## What parts of the international application may be amended?

Under Article 19, only the claims may be amended

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

Witain 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered When? as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of How? one or more of the claims as filed

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

## What documents must/may accompany the amendments?

#### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

Notes to Form PCT/ISA/220 (first sheet) (July 1998; reprint April 2002)

#### NOTES TO FORM PCT/ISA/220 (continued)

The letter must inclicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged:
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where onginally there were 48 claims and after amendment of some claims there are 51]: "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- 2. [Where originally there were 15 claims and after amendment of all claims there are 11]: "Claims 1 to 15 replaced by amended claims 1 to 11."
- 3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
  "Claims I to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added," or
  "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4. [Where various kinds of amendments are made]:
  "Claims 1-10 cmchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

#### -Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the Language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

## Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

# Consequence with regard to translation of the international application for entry into the national phase

The applicant's amention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated elected Office, see the PCT Applicant's Guide,

Notes to Form PCT ISA/220 (second sheet) (July 1998, reprint April 2002)